IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08-948 (LDD)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

APOTEX INC.'S AND APOTEX CORP.'S REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS

Of Counsel:

William A. Rakoczy
Paul J. Molino
Deanne M. Mazzochi
Andrew M. Alul
Neil A. Benchell
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street
Suite 500
Chicago, IL 60654
(312) 222-6301 (telephone)
(312) 222-6321 (facsimile)
wrakoczy@rmmslegal.com (e-mail)

John C. Phillips, Jr. (#110)
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200 (telephone)
(302) 655-4210 (facsimile)
jcp@pgslaw.com (e-mail)

Attorneys for Defendants Apotex Inc. and Apotex Corp.

Dated: June 17, 2009

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes

I. INTRODUCTION

Pfizer's scatter-shot response merely confirms what was apparent from the get-go—Pfizer falls woefully short of establishing personal jurisdiction over Apotex Inc. Pfizer concedes, as it must, that no actual infringement has occurred in Delaware, and that Apotex has not manufactured, sold, offered for sale or used its proposed generic ANDA products in Delaware. (D.I. 36, Pfizer Br. at 2-3). Nor does Pfizer contest the fact that Apotex Inc., a Canadian corporation based solely in Canada, did not prepare or file its ANDA in Delaware; does not own property or employ anyone in Delaware; and has never itself directly sold any products in Delaware. (*See id.* at 4, 10). In short, this action did not arise out of anything that occurred in Delaware, and there is no connection at all between Delaware and Apotex Inc., much less the continuous and systematic contacts necessary for personal jurisdiction. Pfizer's arguments to the contrary are without merit—and if anything, they only serve to highlight the absence of any legitimate basis for exercising jurisdiction over Apotex Inc.

No Specific Jurisdiction. Pfizer has concocted several specific jurisdiction theories, none of which hold any water (or have any legal support whatsoever). For example, Pfizer suggests that a courtesy copy of Apotex Inc.'s Paragraph IV notice letter, which was sent to Pfizer's outside counsel in Delaware, somehow establishes specific jurisdiction. This outlandish argument does not even get off the ground. The statute requires that Paragraph IV notice be sent only to the NDA-holder and patent owner, neither of whom reside in Delaware here. That Apotex sent a courtesy copy of that notice to Pfizer's outside counsel does not and indeed could not give rise to this suit. And even if it could, Delaware courts have rejected the notion that mere mailings into the state give rise to specific jurisdiction. In fact, courts have rejected the very same notice letter theory that Pfizer relies on here—a fact that Pfizer disingenuously neglects to mention. For the same reasons, Pfizer's argument that Apotex Inc. somehow perpetrated a tort

on Pfizer by virtue of sending the notice letter to Pfizer's Delaware outside counsel also fails. No tort or other injury has occurred in Delaware, and certainly nothing sufficient for specific jurisdiction.

No General Jurisdiction. Pfizer's general jurisdiction arguments are equally baseless, beginning with the absurd notion that "litigation is Apotex's regular business activity," and that Apotex Inc. is "conducting its ANDA litigation business in Delaware." (Pfizer Br. at 18 and 21). This argument is not only ludicrous, but would turn the jurisdictional analysis on its head by finding jurisdiction, *not* where the defendant had purposefully availed itself and intentionally established systematic and continuous contacts, but rather where brand companies chose to repeatedly sue the defendant. Pfizer's attempt to establish general jurisdiction based on purported product sales fares no better. Pfizer concedes that Apotex Inc. does not directly sell anything in Delaware. To the extent that Apotex Inc.'s products may end up in Delaware, Pfizer can attempt to establish jurisdiction, if at all, only through a "stream of commerce" theory. But that is a specific jurisdiction theory, and Pfizer concedes that none of those alleged product sales give rise to this suit. Nor are these purported product sales substantial enough to establish general jurisdiction in any event.

Violation of Due Process. Pfizer's due process arguments are circular, and miss the point. Where, as here, Apotex Inc. has no continuous and systematic contacts with Delaware, it certainly wouldn't be fair to drag Apotex Inc. into court here. Pfizer's accusations of jurisdictional "Whac-A-Mole" and "manipulation of the judicial process" are entirely backwards. Apotex was not required to consent to jurisdiction in the venue of Pfizer's choice, and certainly not in a venue where it has no minimum contacts. Rather, it was Pfizer's obligation to bring suit only in a venue in which it has a good faith belief of, and actual facts to support, jurisdiction—

not in a forum where Pfizer's preferred judge sits. Because there are no such facts here, the Court should and indeed must dismiss the action against Apotex Inc. for lack of personal jurisdiction. The Court should also deny Pfizer's backhanded request for jurisdictional discovery for what it is: a fishing expedition based on improper speculation. The Court should also dismiss all claims against Apotex Corp. for lack of an indispensable party. In the alternative, or in the event the Court declines to reach the motion to dismiss, the Court should transfer this action to Illinois where it belongs.

II. ARGUMENT

A. Pfizer Cannot Establish Specific Jurisdiction Over Apotex Inc.

To exercise specific jurisdiction over a defendant, the Court must find that the "suit aris[es] out of or related to the defendant's contacts with the forum[.]" *Helicopteros Nacionales de Colombia, S.A., v. Hall*, 466 U.S. 408, 414, fn. 8 (1984); *see also Hollyanne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1307-08 (Fed. Cir. 1999). Pfizer does not and cannot meet that standard here because nothing in Delaware gives rise to this suit. Pfizer's frivolous arguments do not suggest otherwise.

1. A Courtesy Copy Of Apotex Inc.'s Paragraph IV Notice Letter Does Not And Indeed Cannot Give Rise to Specific Jurisdiction.

Pfizer concedes that Apotex Inc.'s ANDA was not prepared or filed in Delaware, and that no actual sales of the ANDA products have occurred here. Nonetheless, without a shred of support (legal or otherwise), and as proof positive that no good deed goes unpunished, Pfizer suggests that a courtesy copy of Apotex Inc.'s Paragraph IV notice letter, which was sent solely as a courtesy to Pfizer's outside counsel in Delaware, somehow establishes specific jurisdiction here. (*See* Pfizer Br. at 15-17). Pfizer is dead wrong on a number of fronts.

First, and most simply, that courtesy copy had no legal significance whatsoever, and even if it did, it certainly did not give rise to this suit. The statute requires that notice be sent to the NDA-holder and patent owner. *See* 21 U.S.C. § 355(j)(2)(B). Apotex Inc. satisfied its statutory obligation by sending the notice letters to Pfizer Inc. and Pfizer Ireland, the purported NDA-holders, and to Warner-Lambert, the purported patent owner, in New York and Ireland, ***not*** Delaware. The additional courtesy copy sent to Pfizer's outside counsel was just that—a mere courtesy. It was not the actual notice required under the statute. But even if it was, that notice does not give rise to this suit, or otherwise create the subject matter jurisdiction necessary to adjudicate the infringement or validity of Pfizer's patent. Far from it in fact—the artificial act of infringement giving rise to this suit and the Court's subject matter jurisdiction was the filing of the ANDA, which occurred in Maryland, ***not*** Delaware. *See* 35 U.S.C. § 271(e)(2) (it shall be an act of infringement to submit an application); *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 675-76 (1990) (describing the submission of an ANDA as a "somewhat artificial" act of infringement).

Second, courts in this District have made clear that a mere mailing into the district is insufficient as a matter of law. In *Sears, Roebuck & Co. v. Sears PLC*, 744 F. Supp. 1289 (D. Del. 1990), the plaintiff claimed that the "mailing of statements and promotional materials from the United Kingdom constitutes an act in Delaware." *Sears*, 744 F. Supp. at 1294 (internal citations omitted). The court disagreed, holding that "in order for a defendant to commit an act in Delaware and be subject to [Delaware's long-arm statute], the defendant, or an agent of the defendant, must be present in Delaware when the deed is done." *Id.* That, of course, is not the case here.

Third, courts have already rejected the exact same argument that Pfizer trots out here. In *Glaxo Inc. v. Genpharm Pharm., Inc.*, 796 F. Supp. 872, 872 (E.D.N.C. 1992), for example, the plaintiff argued, as Pfizer does here, that the defendant's "mailing of the notice of certification of invalidity . . . to Glaxo, Inc., in North Carolina established specific jurisdiction" because it "was an integral part of the act of patent infringement by the defendant." *Id.* at 876. The court disagreed, holding that this contact is insufficient to support personal jurisdiction, since the defendant "was simply complying with the federal statute," which "was not a purposeful act directed at North Carolina . . . ." *Id.* "Mailing a statutorily-required notice is not akin to soliciting business, introducing products into the forum, or signing and performing a contract within the forum." *Id.*; *see also Celgene Corp. v. Abrika Pharms., Inc.*, 2007 WL 1456156, at *2 (D.N.J. May 17, 2007) (sending the notice letter to plaintiffs without more does not constitute grounds for finding specific jurisdiction).

So, too, here—even if Apotex Inc. had directed its notice letter to the NDA-holder and patent owner in Delaware (and it didn't—the actual statutory notice was sent to New York and Ireland), this contact would not be sufficient to support specific jurisdiction. Any holding to the contrary would turn the jurisdictional inquiry on its head by conferring specific jurisdiction in the jurisdictions where notice must be sent pursuant to statute, and not where the suit actually arose. As the court in *Genpharm* aptly observed, "nothing in the statute or case law suggests that the defendant would be subject to an infringement suit wherever the notice to the approved-NDA holder is mailed." *Genpharm*, 796 F. Supp. at 876.

For the same reasons, Apotex Inc.'s "offer of confidential access" cannot, as Pfizer disingenuously suggests, give rise to specific jurisdiction in Delaware either. As an initial matter, Apotex Inc. made that offer to the NDA-holder and patent owner in New York and

Ireland, ***not*** Pfizer's outside counsel in Delaware. What's more, the offer of confidential access did not give rise to this suit under any scenario. Nor was this offer a "part of [Apotex Inc.'s] overall effort to obtain FDA approval to sell generic atorvastatin." (Pfizer Br. at 15). Quite the contrary, it is merely a requirement for filing a declaratory judgment in the event that Pfizer does not sue. But it has nothing whatsoever to do with obtaining FDA approval.[1] The Court therefore should reject Pfizer's contrived notice letter and offer of confidential access theories.

2. The Events Giving Rise to This Action Did Not Cause Tortious Injury In Delaware.

Apparently realizing that its notice letter theory is entirely frivolous (an understatement), Pfizer falls back on the equally unfounded argument that Apotex Inc. committed a tort and injured Pfizer in Delaware with its ANDA submission, which admittedly was made in Maryland. (Pfizer Br. at 16-17). This, too, fails on a number of grounds. Most notably, as Pfizer expressly concedes, the Federal Circuit—whose precedent controls here—already expressly rejected this argument in *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558 (Fed. Cir. 1994). There, the Federal Circuit held that the situs of the infringement and tort, as well as the, economic loss, "occurs to the patent holder ***at the place where the infringing sale is made*** because the patent owner loses business there." *Beverly Hills Fan*, 21 F.3d at 1571 (emphasis added). As the Federal Circuit more recently acknowledged, "[o]ur cases make clear that the tortuous injury caused by patent infringement occurs within the state where the allegedly infringing sales are made." *Commissariat a L'energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1318 (Fed. Cir. 2005). Accordingly, if there has been any tort here at all,

[1] It also bears noting that Pfizer has already taken the position that Apotex Inc. did not even make a proper offer of confidential access at all under the statute. (*See* June 17, 2009 Declaration of John C. Phillips, Jr., Esq. Ex. C, Mem. in Supp. of Pls.' Mot. to Dismiss Defs.' Countercl.14-17, submitted in *Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-07231 (N.D. Ill)). The Court therefore should reject any argument now that this so-called "offer" establishes specific jurisdiction.

it did not occur in Delaware, where admittedly there have been no sales or any activity of any kind concerning Apotex Inc.'s ANDA.

The best Pfizer can do in response is an invitation to ignore controlling Federal Circuit precedent in favor of older district court decisions whose reasoning the Federal Circuit expressly rejected. (*See* Pfizer Br. at 17). But this, the Court should and cannot do. Pfizer also suggests that the Federal Circuit's ruling in *Beverly Hills Fan* is limited to "traditional patent infringement activity" and should not be extended to "highly artificial infringement" under § 271(e)(2). (*See* Pfizer Br. at 16). The problem for Pfizer, however, is that nothing in *Beverly Hills Fan* limits its holding to so-called traditional infringement, or otherwise excludes infringement under § 271(e)(2). Other Federal Circuit cases are equally "clear that the tortious injury caused by patent infringement occurs within the state where the allegedly infringing sales are made." *Commissariat a L'energie Atomique*, 395 F.3d at 1318.

But even if these cases did not apply in the ANDA setting (and there is no reason they should not), that would not help Pfizer here. As Pfizer concedes, and as the case law makes clear, the so-called "highly artificial" act of infringement is the filing or submission of the ANDA. *See* Pfizer Br. at 16 ("Apotex Inc.'s filing of its ANDA is an act of infringement."); 35 U.S.C. § 271(e)(2) (it shall be an act of infringement to submit an application); *Eli Lilly*, 496 U.S. at 675-76 (describing the submission of an ANDA as a "somewhat artificial" act of infringement). *All parties agree that the filing of the ANDA occurred in Maryland,* ***not*** *Delaware.* Thus, to the extent any tort of patent infringement was committed at all, that tort occurred in Maryland. Nothing regarding the filing of the ANDA could have possibly injured Pfizer in Delaware.

Pfizer also argues that this result, as well as *Beverly Hills Fan,* is somehow "in tension with" the Federal Circuit's decision in *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829 (Fed. Cir. 1999). (Pfizer Br. at 17). Wrong again. Nothing in *Zeneca* holds that the filing of the ANDA in Maryland is *not* a tort. Quite the contrary in fact, the Federal Circuit was very clear that the filing of the ANDA "is a statutory act of patent infringement," which does in fact occur in Maryland. *See Zeneca*, 173 F.3d at 830-31. The only question was whether that act of infringement could secure personal jurisdiction in Maryland. The Federal Circuit held that it could not "in light of the government contacts exception," but not because a tort did not occur in Maryland. *See id.* at 831. Pfizer thus misstates the holding and import of *Zeneca.* There is no "tension," real or imagined, in the Federal Circuit's case law, other than Pfizer's contrived efforts to concoct some type of connection with Delaware, of which there is none here.

The bottom line is that Pfizer has suffered no injury, and Apotex Inc. has committed no tort, in Delaware arising out of the submission of its ANDA. Thus, there is no basis for asserting specific jurisdiction on these grounds either.

B. Pfizer Cannot Establish General Jurisdiction Over Apotex Inc.

Pfizer's general jurisdiction arguments are equally baseless. This requirement "is considerably more stringent than that required for specific jurisdiction," and "must be so extensive to be tantamount to being constructively present in the state." *Eli Lilly & Co. v. Mayne Pharma USA Inc.*, 504 F. Supp. 2d 387, 393 (S.D. Ind. 2007). Pfizer cannot meet that considerable burden here, especially where it does not—and indeed cannot—dispute any of the following facts:

- *First*, Apotex Inc. does not reside, or otherwise maintain any presence of any kind, in Delaware. Rather, Apotex Inc. is a Canadian corporation with its sole place of business in Canada. (D.I. 31, Tao Decl., ¶¶ 4-6).

- *Second*, Apotex Inc. does not maintain offices, facilities, local telephone listings, or bank accounts in Delaware; own or lease any real property in Delaware; have any employees in Delaware; or solicit any business in Delaware. All of Apotex Inc.'s facilities, offices, real estate and employees are located solely in Canada. Nor does Apotex Inc. have any subsidiaries located in Delaware. (D.I. 31, Tao Decl., ¶¶ 8-11).

- *Third*, Apotex Inc. is not registered or licensed to do any type of business in Delaware. Apotex Inc. does all of its research, development and manufacturing in Canada. And, as Pfizer concedes, Apotex Inc. has never directly sold any of those pharmaceutical products in Delaware. (D.I. 31, Tao Decl., ¶¶ 6-7, 17-18).

These undisputed facts preclude the exercise of general jurisdiction over Apotex Inc. Pfizer nonetheless concocts two arguments for why Apotex Inc. is continuously and systematically present in Delaware. Both are baseless, as we explain below.

1. Pfizer Cannot Establish General Jurisdiction Based On Lawsuits Filed Against Apotex Inc. In Delaware.

Pfizer first devotes nearly six full pages to one argument, namely, that Apotex Inc. is somehow subject to general jurisdiction in Delaware because it is involved in ANDA litigation there. (Pfizer Br. at 18-24). But for all the sound and fury of its response, Pfizer cannot point to a single case or other authority, ANDA or otherwise, in support of this absurd proposition—and for good reason, because there is none. In fact, just the opposite is true. As the courts have repeatedly confirmed, including in ANDA cases, "prior litigation within the [forum state] does not support a finding of general jurisdiction." *Abbott Labs. v. Mylan Pharms., Inc.*, 2006 WL 850916, at *6 (N.D. Ill. Mar. 28, 2006) (refusing to find general jurisdiction based on prior litigation in the forum); *see also Wallace v. Int'l Lifestyles, Inc.*, 2008 WL 623811, at *5 (E.D. Pa. Mar. 6, 2008) (finding prior litigation does not necessarily confer personal jurisdiction in Florida such that personal jurisdiction cannot be challenged in Florida); *Rozenblat v. Sandia Corp.*, 2005 WL 1126879, at *2 (N.D. Ill. May 2, 2005) ("[T]he fact that [Defendants] appeared as Defendants in another action in the [forum state] does not mean that they waived all personal

jurisdiction requirements for future actions."); *United States v. Subklew*, 2001 WL 896473 (S.D. Fla. June 5, 2001) (finding no personal jurisdiction despite the fact that defendant had defended an action in the same forum). Tellingly, Pfizer is unable to point to a single case which held otherwise.[2] For this reason alone, the Court can and should reject Pfizer's litigation argument.

Nor has Pfizer given this Court any reason to adopt a special litigation exception or rule for general jurisdiction purposes, or otherwise re-write the law of general jurisdiction. Indeed, any such holding would turn the jurisdictional analysis on its head by finding and subjecting the defendant to jurisdiction, *not* where the defendant had purposefully availed itself and intentionally established and maintained regular and systematic contacts, but rather wherever brand companies chose to repeatedly sue the defendant. In other words, under Pfizer's distorted view, a plaintiff could effectively dictate where a defendant could be sued and subjected to general jurisdiction merely be repeatedly suing that defendant in a particular forum. But the law of general jurisdiction focuses on where the defendant purposefully maintains continuous and systematic contacts, not where various plaintiffs have chosen to sue that defendant in prior actions. Pfizer's theory thus makes no practical or legal sense, and would effectively create a new rule or exception solely for ANDA defendants (that are repeatedly sued in a particular forum)—a rule that would clearly violate due process and offend traditional notions of fair play and substantial justice. That is reason enough to reject it out of hand.

The prior litigations on which Pfizer bases this argument also make clear that Apotex Inc. was not waiving or otherwise consenting to jurisdiction in Delaware for all future matters. As

[2] Pfizer's reliance on *Colonial Martgage Serv. Co. v. Aerenson*, 603 F. Supp. 323 (1985) is unavailing. There, the court found that, aside from "repeatedly invok[ing] the benefits of the Delaware state courts to protect its interests" which were located in Delaware, the defendant also "ha[d] entered into some 200 loan agreements with Delaware mortgagors, [and] placed millions of dollars at risk in Delaware property[.]" *Colonial*, 603 F. Supp. at 327. By contrast, Apotex Inc. holds no property in Delaware, nor does it sell directly into the state, and has only once invoked the Delaware state courts to protect its ability to market its generic products by filing a declaratory judgment action.

Apotex Inc. set forth in its opening brief, not including the present suit, Apotex Inc. has been a named defendant in at least eleven ANDA suits in Delaware.[3] Apotex Inc. challenged jurisdiction in one suit, but the motion was denied without prejudice and without an adjudication on the merits. *See AstraZeneca Pharms. LP, et al. v. Apotex Inc., et al.*, No. 07-809 (D. Del. 2007). In another suit, the case was dismissed before an answer was filed. *See Purdue Pharma. L.P., et al. v. Apotex Inc., et al.*, No. 07-549 (D. Del. 2007). In most of the remaining suits (9), Apotex Inc. either did not contest, or otherwise submitted to, the jurisdiction of the court, ***solely for purposes of that particular action***—which does not constitute an admission of general jurisdiction for all purposes. *See Sanofi-Aventis, et al. v. Apotex Inc., et al.*, No. 07-792 (D. Del. 2007); *Senju Pharm. Co., Ltd., et al. v. Apotex Inc., et al.*, No. 07-779 (D. Del. 2007); *Allergan, Inc. v. Apotex Inc., et al.*, No. 07-278 (D. Del. 2007); *MedPointe Healthcare Inc., v. Apotex Inc., et al.*, No. 07-204 (D. Del. 2007); *MedPointe Healthcare Inc. v. Apotex Inc., et al.*, No. 06-164 (D. Del. 2006); *Boehringer Ingelheim Pharms., Inc. v. Apotex Inc., et al.*, No. 08-65 (D. Del. 2008); *Merck & Co., Inc. v. Apotex Inc.*, No. 06-230 (D. Del. 2006); *Sanofi-Aventis et al. v. Apotex Inc., et al.*, No. 08-347 (D. Del. 2008); *Aventis Pharma S.A., et al. v. Apotex Inc., et al.*, No. 08-496 (D. Del. 2008). None of these cases constitutes a general consent to jurisdiction in Delaware for all cases and all purposes. Pfizer also conveniently omits that in none of the cases was there ever a judicial finding or determination that Apotex Inc. is subject to general jurisdiction in Delaware.

That Apotex Inc. once filed a declaratory judgment action in Delaware, which was dismissed for lack of subject matter jurisdiction, does not change the analysis. *See Apotex Inc., et al. v. Pfizer Inc., et al.*, No. 03-990 (D. Del. 2003). And it certainly does not establish, as

[3] Apotex Inc. was just recently sued in Delaware again in *Pronova BioPharma Norge AS v. Apotex Corp. et al.*, Case No. 1:09-cv-304 (D. Del.). Apotex Inc. has not yet responded to the complaint in that action.

Pfizer seems to suggest, that Apotex Inc. is continuously and systematically present here. (Pfizer Br. at 22). Indeed, to borrow from the D.C. District Court, "[i]t would be ludicrous to suggest that [Apotex Inc.] consented to the jurisdiction of this Court for all time, with respect to all potential competitors, and for all purposes, simply because they once chose to sue [Pfizer] here." *Mallinckrodt Med. Inc. v. Sonus Pharms., Inc.*, 989 F. Supp. 265, 271 (D.D.C. 1998).

Pfizer's argument that Apotex Inc. has "engaged the services of Delaware law firms to represent it and presumably paid the law firms substantial sums" also misses the mark. (Pfizer Br. at 23). Apotex Inc. engaged those firms precisely because it was sued, against its will, at least eleven times (not including this suit). But surely Apotex Inc. cannot be faulted or otherwise penalized for defending itself in court by retaining counsel. This fact cannot be used against Apotex Inc. any more than the fact of the suits themselves. Doing so would subject Apotex Inc. to general jurisdiction not where it purposefully maintains systematic and continuous contacts, but rather wherever the brand companies chose to sue it. The general jurisdiction analysis cannot, and should not, depend on the whim of the plaintiffs that previously sued Apotex Inc.

Pfizer's repeated bluster about the Hatch-Waxman Act also misses the point. (*See* Pfizer Br. at 18-21). To be sure, Hatch-Waxman provided a mechanism for resolving any patent disputes before actual marketing of the generic drug. But contrary to Pfizer's assertions, Hatch-Waxman neither mandates that actual litigation occur, nor dictates the forum in which such litigation must be filed. Rather, it is the brand companies like Pfizer that decide whether and where to bring suit, just as Pfizer did here. Perhaps even more importantly, Hatch-Waxman did nothing to change the law or rules of general jurisdiction. A brand company like Pfizer must still file suit only where it has a good faith belief, and actual facts to prove, that the ANDA defendant is subject to jurisdiction, either specifically or generally. Hatch-Waxman does not alleviate or otherwise alter that burden.

Pfizer's unfounded assertions that Apotex Inc. is in the "ANDA litigation business" are ludicrous, if not absurd. (Pfizer Br. at 21). Apotex Inc., like Pfizer, develops and manufactures pharmaceutical products. Apotex Inc. is no more in the "litigation business" than Pfizer. It is true that Apotex Inc. litigates ANDA cases, but only because it is forced to do so by the brand companies like Pfizer that file suit against it in order to maintain their lucrative drug monopolies. But again, this does not bear on the jurisdictional analysis, and is just another variation on Pfizer's theme that a defendant is subject to general jurisdiction where it is repeatedly sued. As noted above, that is not now, and never has been, the law.

The bottom line is that Apotex Inc. has not "systematically and regularly resorted to Delaware Courts as an integral part of its generic drug business," as Pfizer suggests. (Pfizer Br. at 23). Rather, it is the brand companies like Pfizer, seeking to protect their drug monopolies, that have "systematically and regularly resorted to" the Delaware courts. But that just makes Delaware a forum of choice for brand companies. It does not establish general jurisdiction over Apotex Inc.

2. Pfizer's "Stream-Of-Commerce" Theory Fails.

Pfizer's second general jurisdiction argument is that Apotex Inc.'s generic products have been sold in Delaware, including $2.8 million in sales in 2008. (Pfizer Br. at 24). Notably, however, Pfizer does not, and indeed cannot, argue that Apotex Inc. has directly sold anything in Delaware. In fact, Pfizer does not seriously contest that Apotex Inc. does not directly sell or market any products in Delaware. (*See id.*) Rather, Pfizer concedes that such products were sold or ended up in Delaware as a result of sales by others. (*Id.*) The purported IMS data that Pfizer exclusively relies on bears this out—it does not show a single Delaware sale by Apotex Inc. (*See* D.I. 37-7 - D.I. 37-19, Mulveny Decl., Ex. W). According to the IMS data, all such sales were purportedly made by Apotex Corp., an independent affiliate and U.S. corporation that is neither owned nor controlled by Apotex Inc., and which is not challenging jurisdiction. But even such

sales of Apotex Inc.'s products by others occurred in Delaware as Pfizer asserts, that does not establish general jurisdiction over Apotex Inc. It is true that "under certain circumstances, the indirect sale through a distributor of a defendant's product in the forum state may constitute purposeful availment and may make a court's exercise of personal jurisdiction reasonable." *See Zeneca Ltd. v. Mylan Pharms., Inc.*, 1996 WL 925640, at *3 (D. Md. Jan. 6, 1996). But it is equally well-settled that "[j]urisdiction based on the 'stream of commerce' theory is only proper, though, *when the suit arises from the products which the corporation has placed into commerce in this way*." *Id.* (emphasis added). Courts in this district have also confirmed that "stream of commerce is a theory of specific jurisdiction." *Power Integrations, Inc. v. BCD Semiconductor Corp.*, 547 F. Supp. 2d 365, 371 (D. Del. 2008); *see also Renner v. Lanard Toys Ltd.*, 33 F.3d 277 (3rd Cir. 1994) (stream of commerce theory establishes specific jurisdiction over a defendant). Thus, it does not matter for general jurisdiction purposes how many of Apotex Inc.'s products are indirectly sold or "stream" into Delaware through Apotex Corp. or others, *unless the litigation actually arises out of those contacts or sales*.

Here, of course, Pfizer freely concedes that none of the alleged product sales made by Apotex Corp. in Delaware gave rise to this litigation—and indeed, those alleged sales all involved completely unrelated products. Where, as here, the unrelated products distributed through the stream of commerce or distribution network admittedly do not give rise to the suit, the Court may not maintain jurisdiction over Apotex Inc. under a stream-of-commerce analysis.

Pfizer's reliance on *LSI Indus., Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369 (Fed. Cir. 2000), is misplaced and does not hold otherwise. There, the court affirmed a finding of general jurisdiction based on the movant's (Hubbell) failure to "mount a significant challenge to the court's exercise of jurisdiction," and "[b]ased on Hubbell's millions of dollars of sales of lighting

products in Ohio over the past several years and its broad distributorship network in Ohio." *Id.* at 1375. In other words, the movant itself sold millions of dollars of product in Ohio and directly employed a distribution network to do so. Here, by contrast, Apotex Inc. is not directly selling anything in Delaware, nor directly employing anyone else to do so. (D.I. 31, Tao Decl., ¶¶ 7-14). Indeed, Apotex Corp.—which is purportedly distributing Apotex Inc.'s products in Delaware—is not even a subsidiary of Apotex Inc., but rather a stand-alone corporate affiliate that is neither owned nor controlled by Apotex Inc. (D.I. 31, Tao Decl., ¶ 28). Accordingly, that Apotex Inc.'s other, unrelated products may have been "sold, distributed and used in the state of Delaware" is irrelevant absent a connection between those contacts and this suit, of which there admittedly is none.

3. Apotex Inc. Is Not Subject To General Jurisdiction Under Any Other Sales Theory.

Even assuming that Apotex Inc. had directly sold the purported $2.8 million in generic products in Delaware in 2008 (which even by Pfizer's own admission it admittedly did not), that would still be insufficient as a matter of law to establish general jurisdiction. Indeed, those sales would represent but a tiny fraction of Apotex Inc.'s total worldwide sales. According to the web page submitted and relied upon by Pfizer, Apotex Inc.'s worldwide sales exceed $1 billion Canadian per year. So even using a conservative exchange rate, those purported Delaware sales that Pfizer relies on would account for no more than about 0.32% of Apotex Inc.'s total sales—or much less than 1%. By any standard or measure, that is far from "substantial," and certainly insufficient to establish a systematic and continuous presence in Delaware.

In fact, courts have routinely dismissed actions where the defendant had much more substantial contacts with the forum state. In *Zeneca Ltd. v. Mylan Pharms., Inc.*, the generic ANDA applicant actually maintained a sales representative to call directly on customers in

Maryland, and also had contacts with a regulatory consultant in the state. Sales in the forum state were estimated to be $5 million, or less than 1% of the defendant's total revenue. The Court held that such activities did not constitute "general and systematic" contacts with Maryland to satisfy general jurisdiction. *See Zeneca*, 1996 WL 925640 at *6. So, too, did the court in *Merck*, where the generic ANDA applicant was a corporation with sales in the forum state of approximately $587,000 for one particular year that the court considered accounting for about 0.13% of total revenues. The court held that such contacts did not amount to regularly doing or soliciting business in Delaware, and therefore were insufficient to establish general jurisdiction. *Merck & Co. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 374 (D. Del. 2002).

Recently, this Court considered a motion to dismiss for lack of personal jurisdiction in another ANDA case with almost identical facts. In that case, two related Defendants asked the Court to dismiss the complaint because, just as here, neither movant had any contact with Delaware. *See Forest Labs. Inc. v. Cobalt Labs. Inc.*, 2009 WL 605745, *1 (D. Del. Mar. 9, 2009). The Court acknowledged, just like Apotex Inc. here, that the movants do not have "any offices, facilities, employees, telephone listings, bank accounts, or property in Delaware; neither are registered to do business or sell pharmaceuticals here; nor do they advertise, derive substantial revenues or initiate litigation here." *Id.* at *8. The only presence the two movants had in the state was a wholly-owned subsidiary of the first movant whose sole purpose was to incorporate the second movant. *Id.* at *2. Thus, the Court characterized the intervening company as "essentially a shell corporation." *Id.* Plaintiffs nonetheless argued that the movants' contacts with Delaware, which were even more substantial than here, included purchase of materials used in the generic products from Delaware companies, use of a Delaware corporation for "analytic services," the existence of distribution agreements with Delaware companies,

clinical trials preformed in Delaware which were submitted with the Defendants' ANDA, sales representatives' visit to Delaware, and the existence of Service Agreements which are governed by Delaware law. *See id.* at *3-*5. Even in view of the litany of connections with Delaware Plaintiffs attempted to assert, the court concluded that, "[i]n sum, the record does not demonstrate continuous and systematic contacts between [the movants] and Delaware. Plaintiffs have failed to meet their burden to establish general jurisdiction." *Id.* at *9. The same is true here.

C. The Exercise of Personal Jurisdiction Over Apotex Inc. Would Offend Traditional Notions of Fair Play and Substantial Justice.

Pfizer's ridiculous notice letter theories aside, nothing about this action arose or occurred in Delaware. Apotex Inc., moreover, has no contacts there, much less systematic and continuous ones. In these circumstances, the exercise of jurisdiction would violate the most basic tenets of due process, thus requiring dismissal as a matter of law. *See Carvel v. Griffin*, 2008 WL 4922432, at *7 (D. Del. Nov. 18, 2008) (granting motion to dismiss for lack of personal jurisdiction due to insufficient contacts with forum state); *Shoemaker v. McConnell*, 556 F. Supp. 2d 351, 355 (D. Del. 2008) (granting motion to dismiss for lack of personal jurisdiction because exercise of the jurisdiction would not comport with due process); *Kee v. Blue Line Distrib., Inc.*, 587 F. Supp. 2d 636, 640 (D. Del. 2008) (Farnan, J.) (granting motion to dismiss for lack of personal jurisdiction due to insufficient "substantial and continuous" contacts with forum).

Pfizer's only argument is that *declining* jurisdiction would "legitimize Apotex Inc.'s strategy of hiding behind the Canadian border . . . ." (Pfizer Br. at 27). Nonsense. As an initial matter, Pfizer again turns the jurisdictional analysis on its head—if Pfizer, and Pfizer alone, cannot establish the minimum contacts necessary to satisfy due process, there is no legitimate suit to be brought here in the first place. Apotex Inc., moreover, is not hiding behind anything,

much less the Canadian border. Apotex Inc. has already consented to suit in Illinois, where Pfizer filed an identical action. The exercise of jurisdiction here would not only violate due process, but also legitimize Pfizer's filing of duplicative suits.

D. Pfizer Is Not Entitled To Embark On A Fishing Expedition For Jurisdictional Discovery.

The Court should deny Pfizer's request for jurisdictional discovery in its entirety. Indeed, a court is well within its discretion to deny jurisdictional discovery "when the plaintiff fails to establish a prima facie showing of personal jurisdiction." *Knierim v. Siemens Corp.*, 2008 WL 906244, at *11 (D.N.J. Mar. 31, 2008); *see also Hansen v. Neumueller GmbH*, 163 F.R.D. 471, 475 (D. Del. 1995) ("[T]he memoranda which have been filed in response to defendants' motion contain speculation, but no facts by which jurisdiction can be established . . . ." (quoting *Poe v. Babcock Int'l, PLC*, 662 F. Supp. 4, 7 (M.D. Pa. 1985))). Here, Pfizer has not even attempted to present or dispute any facts about any contacts that Apotex Inc. may have with Delaware. Nor has Pfizer even come close to establishing a prima facie case of jurisdiction. As this Court has found in similar cases, "[i]t would be inappropriate for this court to allow [Pfizer] to conduct a fishing expedition in order to construct a basis for jurisdiction." *Hansen*, 163 F.R.D. at 475.

III. CONCLUSION

In short, this litigation does not belong in Delaware. Nothing that triggered this litigation occurred in Delaware, and Apotex Inc. has no presence in Delaware, much less the continuous and systematic presence necessary for jurisdiction. The Court should therefore dismiss all claims against Apotex Inc. for lack of personal jurisdiction and allow this dispute to proceed in Illinois, where Pfizer has filed an identical action. The Court should also dismiss all claims against Apotex Corp. for lack of an indispensible party, thus dismissing the Complaint in its entirety.

Or, in the alternative, of if the Court declines to reach this motion, the Court can and should transfer this action to Illinois (which Pfizer itself does not contest in the event jurisdiction is lacking).

Dated: June 17, 2009

Respectfully submitted,

By: /s/John C. Phillips, Jr.
John C. Phillips, Jr. (#110)
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806
Tel. (302) 655-4200
Fax (302) 655-4210

Of Counsel:
William A. Rakoczy, Esq.
Paul J. Molino, Esq.
Deanne M. Mazzochi, Esq.
Andrew M. Alul, Esq.
Neil A. Benchell, Esq.
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard St., Suite 500
Chicago, Illinois 60654
(312) 222-6301
(312) 222-6321

Attorneys for Defendants Apotex Inc. and Apotex Corp.